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EXAMINER

HOUSTON, ELIZABETH

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/684,942	Applicant(s) KROLIK ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/01/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-37, 39 and 68-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-37, 39, 68-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 36 states, "the proximal end of the retrieval adapter is capable of being coupled to a distal end of an interventional device," which is equivalent to amended claim 1 that states, "the proximal end of the retrieval adapter is configured to" ... "couple with a distal end of the interventional device".

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 31, 32, 35-36 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene et al. (USPN 6,485,501) in view of Grayhack (US 4,611,594) in view of Bagaoisan et al. (USPN 6,152,909).**

4. Greene discloses an apparatus for use in retrieving a vascular filter disposed on a guidewire from a vessel (see figures 28-31), the apparatus comprising: a retrieval

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adapter (392, 380, 397) having a proximal end, a distal end and a lumen; wherein the proximal end of the retrieval adapter is configured to be engaged and be coupled to a distal end of an interventional device within the vessel (Figs 30 and 31 both show that the retrieval adaptor is engaged and coupled with a distal end of an interventional device within the vessel. NOTE that the terminology "engage" and "couple" are being treated as adjectives that describe the apparatus being claimed and not as verbs which would be indicating method); and wherein, when in a non-expanded configuration, at least a portion of the distal end of the retrieval adaptor is tapered and has an inward bend opening (Note all embodiments in Figs. 28-30 show a distal end that tapers inward thus resulting in an inward bend). It is inherent, if not then obvious, that the device would be made of biocompatible material in order for it to be delivered to the body without causing contraindications within the body.

5. Greene does not disclose that the distal end of the retrieval adapter is configured to radially expand. However, Grayhack discloses retrieval catheter (Fig. 7) with a distal end that is configured to radially expand and receive at least a portion of the grasping device within the lumen during retrieval of the vascular filter from the vessel in order to protect the expanded grasping device from injuring tissue. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the feature of expanding the distal end of the filter retrieval device disclosed by Greene in order to protect the expanded filter from injuring healthy tissue during its removal.

6. Greene modified by Grayhack does not disclose that the retrieval adaptor includes an opening oblique to the longitudinal axis. However, Bagaoisan discloses a

catheter that is used in the removal of material from a lumen. The distal tip can be perpendicular to the longitudinal axis or oblique to the longitudinal axis (see figs. 8a, 8b and 8c). Bagaosian teaches that the angled tip maximizes the area opening for ease of retrieval (Col 12, lines 1-10). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the angled tip as disclosed by Bagaosian to enhance the retrieval catheter of Greene in order to provide a wider opening for more easily receiving the filter device without increasing the overall diameter of the retrieval device. The manner of enhancing a particular device was made part of the ordinary capabilities of one skilled in the art based upon the teaching of such a technique by Bagaosian. Accordingly, one of ordinary skill in the art would have been capable of applying this known technique of an oblique opening in the same manner to the prior art filter retrieval of Greene and the results would have been predictable, namely, one skilled in the art would have readily recognized that an oblique opening in a filter retrieval device would positively result in a more effective retrieval device with a streamlined profile for use in narrow vessels.

7. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene in view of Grayhack and Bagaosian et al. as applied to claim 31 above and further in view of Ferrera (USPN 6,240,231).

8. Greene in view of Bagaosian discloses the invention substantially as claimed as stated above except for the radiopaque coil.

9. Ferrera teaches that it is old and well known in medical devices to combine the use of a radiopaque marker that is a reinforcing coil (138, abstract).

10. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a radiopaque marker that is a reinforcing coil into the filter retrieval device since it is an old and well-known technique in the medical field.

Radiopaque markers provide the advantage of enhancing visibility and of the device during delivery. Reinforcing coils provide the advantage of increasing trackability across tortuous vessels and providing additional support. Incorporating these two features into the filter retrieval device would allow the user to track the location of the retrieval device relative to the filter while also providing additional support at the location where the retrieval device will have to carry the weight of the filter and any debris that is being removed. The manner of enhancing a particular device was made part of the ordinary capabilities of one skilled in the art based upon the teaching of such a technique by Ferrera. Accordingly, one of ordinary skill in the art would have been capable of applying this known technique of a radiopaque coil in the same manner to the prior art filter retrieval of Greene modified by Bagaoisan and the results would have been predictable, namely, one skilled in the art would have readily recognized that radiopaque coil in a filter retrieval device would positively result in a more effective retrieval device with increased trackability and visibility.

11. Claims 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greene et al. (USPN 6,485,501) in view of Grayhack and Bagaoisan et al. (USPN 6,152,909) as applied to claim 31 above and further in view of Ha (USPN 6,159,195).

12. Greene modified by Bagaoisan discloses all the elements substantially as claimed as stated above including that the proximal end of the retrieval adapter is tapered to facilitate engagement with a distal end of the interventional device (see Figs 30 and 31). Greene modified by Bagaoisan does not disclose that the distal end of the retrieval adapter has a plurality of expansion slits.

13. Ha discloses an exchange catheter that incorporates the use of slits to accommodate the delivery of an occlusive device while still maintaining a low profile (214; abstract; C 8: L 48-55; C 11: L 55-64). The slits divide the distal portion into a plurality of curved portions since the end of the catheter is round.

It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate expansion slits into the retrieval device of Greene modified by Bagaoisan since the manner of enhancing a particular device was made part of the ordinary capabilities of one skilled in the art based upon the teaching of such improvements by Ha. Accordingly, one of ordinary skill in the art would have been capable of applying the known technique of expansion slits in the same manner to the prior art of the filter retrieval device of Greene modified by Bagaoisan and the results would have been predictable to one of ordinary skill in the art, namely, one skilled in the art would have readily recognized that expansion slits in filter retrieval device would positively result in a device that can readily accommodate the retrieval of a filter while maintaining a low profile.

14. **Claims 68, 69, 72 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene et al. (USPN 6,485,501) in view of Grayhack (US 4,611,594) in view of Bagaoisan et al. (USPN 6,152,909) as applied above and further in view of Bleam (US 6,143,016).**

15. Modified Greene provides the device substantially as claimed as stated except for a second retrieval adapter. However, Greene does disclose the use of a guide sheath in a different embodiment (Figs. 33a-c) for use in smoothly delivering and retrieving the interventional device (balloon and stent) and the filter together. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an outer sheath into the embodiments of Figs. 29-31 in order to smoothly facilitate delivery and retrieval of the devices through the lumen. The use of an additional sheath ensures a low profile of the balloon and filter during delivery and removal, prevents injury caused by the devices to the surrounding tissue during delivery and removal, and ensures that the embolic material does not get dislodged from the filter during removal.

16. Greene does not disclose that the retrieval sheath has a tubular body and a support wire. However Bleam discloses two embodiments of a delivery sheath (Fig. 1 and 11): one that is a distal sheath (34) with a proximal tube (36) that extends the entire length of the catheter (Fig. 1) (similar to Greene) and one that is a distal sheath (34) with a support wire (88) that replaces the proximal tube (Fig. 11). Bleam disclose the advantages of the embodiment of Fig. 11 include the ability to use it with a rapid exchange catheter and the ability for the user to easily maintain a grasp on the inner

catheter while inserting and retrieving the sheath (C8:L48-C9:L25). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate this feature into modified device if Greene to achieve the same advantages.

17. Claims 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene in view of Grayhack, Bagaoisan and Bleam et al. as applied to claim 68 above and further in view of Ferrera (USPN 6,240,231).

18. Modified Greene discloses the invention substantially as claimed as stated above except for the radiopaque coil.

19. Ferrera teaches that it is old and well known in medical devices to combine the use of a radiopaque marker that is a reinforcing coil (138, abstract).

20. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a radiopaque marker that is a reinforcing coil into the filter retrieval device since it is an old and well-known technique in the medical field.

Radiopaque markers provide the advantage of enhancing visibility and of the device during delivery. Reinforcing coils provide the advantage of increasing trackability across tortuous vessels and providing additional support. Incorporating these two features into the filter retrieval device would allow the user to track the location of the retrieval device relative to the filter while also providing additional support at the location where the retrieval device will have to carry the weight of the filter and any debris that is being removed. The manner of enhancing a particular device was made part of the ordinary capabilities of one skilled in the art based upon the teaching of such a technique by

Ferrera. Accordingly, one of ordinary skill in the art would have been capable of applying this known technique of a radiopaque coil in the same manner to the prior art filter retrieval of Greene modified by Bagaoisan and the results would have been predictable, namely, one skilled in the art would have readily recognized that radiopaque coil in a filter retrieval device would positively result in a more effective retrieval device with increased trackability and visibility.

21. Claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greene et al. (USPN 6,485,501) in view of Grayhack, Bagaoisan et al. and Bleam as applied to claim 68 above and further in view of Ha (USPN 6,159,195).

22. Modified Greene discloses all the elements substantially as claimed as stated above including that the proximal end of the retrieval adapter is tapered to facilitate engagement with a distal end of the interventional device (see Figs 30 and 31). Greene modified by Bagaoisan does not disclose that the distal end of the retrieval adapter has a plurality of expansion slits.

23. Ha discloses an exchange catheter that incorporates the use of slits to accommodate the delivery of an occlusive device while still maintaining a low profile (214; abstract; C 8: L 48-55; C 11: L 55-64). The slits divide the distal portion into a plurality of curved portions since the end of the catheter is round.

24. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate expansion slits into the retrieval device of Greene modified by Bagaoisan since the manner of enhancing a particular device was made part of the

ordinary capabilities of one skilled in the art based upon the teaching of such improvements by Ha. Accordingly, one of ordinary skill in the art would have been capable of applying the known technique of expansion slits in the same manner to the prior art of the filter retrieval device of Greene modified by Bagaoisan and the results would have been predictable to one of ordinary skill in the art, namely, one skilled in the art would have readily recognized that expansion slits in filter retrieval device would positively result in a device that can readily accommodate the retrieval of a filter while maintaining a low profile.

Response to Arguments

Applicant's arguments filed 04/01/09 have been fully considered but they are not persuasive. Applicant argues that the device of Greene does not meet the limitation "wherein the proximal end of the retrieval adapter is configured to engage and couple with a distal end of an interventional device within the vessel" since the retrieval device is already included as the distal end of the interventional device. However, applicant is reminded that the pending claims are directed toward an apparatus and not a method. Thus it does not matter how or where the engaging and coupling occurs as long the as final product disclosed is a device that has a retrieval adapter that is engaged (thus capable of being engaged) and coupled (thus capable of being coupled) to the interventional device when the interventional device is within the vessel. This is clearly shown in Figs. 29 and 30 of Greene. In other words the language of the claim is not being treated as a method step but rather functional language that imparts some structure into the claimed apparatus.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
7/17/2009